Medicrea International S.A.S. (Medtronic)
Hajar BOULMAN
Sr Regulatory Affairs Specialist
5389 Rte. De Strasbourg - Vancia
Rillieux-La-Pape, 69140
France

May 15, 2026

Re: K261289
Trade/Device Name: UNiD™ Spine Analyzer (SW3002)
Regulation Number: 21 CFR 892.2050
Regulation Name: Medical image management and processing system
Regulatory Class: Class II
Product Code: QIH, LLZ
Dated: April 17, 2026
Received: April 20, 2026

Dear Hajar BOULMAN:

We have reviewed your section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (the Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database available at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR Part 803) for devices or postmarketing safety reporting (21 CFR Part 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See

the DICE website (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Jessica Lamb, Ph.D.
Assistant Director
Imaging Software Team
DHT8B: Division of Radiological Imaging Devices and Electronic Products
OHT8: Office of Radiological Health
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

Indications for Use

Please type in the marketing application/submission number, if it is known. This textbox will be left blank for original applications/submissions.	K261289

Please provide the device trade name(s).

UNiD™ Spine Analyzer (SW3002)

Please provide your Indications for Use below.

The UNiD™ Spine Analyzer is intended for assisting healthcare professionals in viewing and measuring images as well as planning orthopedic surgeries. The device allows surgeons and service providers to perform generic, as well as spine related measurements on images, and to plan surgical procedures. The device also includes tools for measuring anatomical components for placement of surgical implants. Clinical judgment and experience are required to properly use the software.

Please select the types of uses (select one or both, as applicable).	☒ Prescription Use (21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)
Please select the age group(s) for which the device(s) is to be used.	☐ Neonates/Newborns (Birth to < 29 days old) ☐ Infants (29 days old to < 2 years old) ☒ Children (2 years old to < 12 years old) ☒ Adolescents (12 years old to < 22 years old) ☒ Adults (22 years old and greater)

510(k) Summary

As required by 21 CFR 807.87(h)

The 510(k) Summary is presented on the next page.

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510(k) Summary
UNiD™ Spine Analyzer

Date prepared: April 17, 2026

I. Submitter information		
Submitter	MEDICREA INTERNATIONAL S.A.S. (MEDTRONIC) 5389 Route de Strasbourg – Vancia Rillieux-la-Pape, 69140 France Phone : 00 33 4 72 01 87 87	
Contact Person	Hajar BOULMAN Sr Regulatory Affairs Specialist MEDTRONIC	
II. Device identification		
Trade name	UNiD™ Spine Analyzer	
Classification Regulation	**Common Name**	Automated radiological image processing software
	Primary Product Code	QIH
	Associated Product Code	LLZ
	Regulation Number	21 CFR 892.2050
	Regulation Name	Medical Image Management and Processing System
	Class	2
III. Predicate and reference devices		
Primary predicate device	**Device name**	UNiD™ Spine Analyzer 5.0.0
	510(k) information	K251629, cleared on 08/07/2025
	Common Name	Automated radiological image processing software
	Primary Product Code	QIH
	Product Code	LLZ
	Regulation Number	21 CFR 892.2050
	Regulation Name	Medical image management and processing system
	Class	2

IV. Subject device description

The device description is identical to the predicate device.

The UNiD™ Spine Analyzer is a web-based application developed to perform preoperative and postoperative patient image measurements and simulate preoperative planning steps for spine surgery. It aims to make measurements on a patient image, simulate a surgical strategy, draw patient-specific rods or choose from a pre-selection of standard implants. The UNiD™ Spine Analyzer allows the user to:

1. Measure radiological images using generic tools and “specialty” tools
2. Plan and simulate aspects of surgical procedures
3. Estimate the compensatory effects of the simulated surgical procedure on the patient’s spine

The planning of surgical procedures is done by Medtronic as part of the service of pre-operative planning. The surgical plan may then be used to assist in designing patient-specific implants. Surgeons will have to validate the surgical plan before Medtronic manufactures any implant.

The UNiD™ Spine Analyzer interface is accessible in either standalone mode or connected mode.

V. Intended use and indications for use	
Intended use / Indications for use	*The intended use/indications for use are identical to the predicate device.* The UNiD™ Spine Analyzer is intended for assisting healthcare professionals in viewing and measuring images as well as planning orthopedic surgeries. The device allows surgeons and service providers to perform generic, as well as spine related measurements on images, and to plan surgical procedures. The device also includes tools for measuring anatomical components for placement of surgical implants. Clinical judgment and experience are required to properly use the software.

VI. Comparison of technological characteristics

The subject device has similar fundamental scientific technology, overall design, features, computer configuration characteristics, intended use, and indications as the predicate device. The subject device and the predicate device are intended to assist healthcare professionals in viewing and measuring images as well as planning orthopedic surgeries.

The main software modifications incorporated into UNiD™ Spine Analyzer 5.1.0, as compared with the predicate device, are summarized below:

- update the communication of the UNiD Spine Analyzer from UNiD™ HUB to Gaiteway™;
- unblocking of Degenerative Predictive Model in cases where femoral heads are not visible on the image, using an indirect method based on a secondary image;
- transfer and correction of the L1-L4 and L4-S1 calculation from Lambda application to the UNiD™ Spine Analyzer system;
- update of the Predict Tool to prevent selection of a UIV/LIV outside the model's specification;
- bug fixes in measurement tools and related workflows; and
- cybersecurity fixes.

The subject device and the predicate device are compared in the table below.

Feature/ Attribute	**Subject Device** **UNiD™ Spine Analyzer 5.1.0**	**Predicate** **UNiD™ Spine Analyzer 5.0.0** **(K251629)**
Product code(s)	QIH, LLZ	QIH, LLZ
Regulation number	892.2050	892.2050
Classification	2	2
Intended use / Indications for use	The UNiD™ Spine Analyzer is intended for assisting healthcare professionals in viewing and measuring images as well as planning orthopedic surgeries. The device allows surgeons and service providers to perform generic, as well as spine related measurements on images, and to plan surgical procedures. The device also includes tools for measuring anatomical components for placement of surgical implants. Clinical judgment and experience are required to properly use the software.	The UNiD™ Spine Analyzer is intended for assisting healthcare professionals in viewing and measuring images as well as planning orthopedic surgeries. The device allows surgeons and service providers to perform generic, as well as spine related measurements on images, and to plan surgical procedures. The device also includes tools for measuring anatomical components for placement of surgical implants. Clinical judgment and experience are required to properly use the software.

Fundamental scientific technology	Standalone software	Standalone software
Computer	PC Compatible	PC Compatible
Operating System	Windows + Mac	Windows + Mac
Supply mean	Cloud-based	Cloud-based
Health Data Host	AWS	AWS
Frontend code	Angular 14 & Angular JS 1.7	Angular 14 & Angular JS 1.7
Backend code	.NET 8.0	.NET 8.0
Databases server	SQL Server	SQL Server
Human intervention	Required for interpretation and manipulation of images	Required for interpretation and manipulation of images
Supported image format	JPEG; PNG; GIF	JPEG; PNG; GIF
Access mode	**Standalone** or connected mode (via **Gaiteway** software)	Standalone or connected mode (via **UNiD™** HUB software)
Feature - Image setting	Contrast; brightness; zoom in/out; flip, rotate, text overlay, calibration	Contrast; brightness; zoom in/out; flip, rotate, text overlay, calibration
Feature - Generic measurements tools	Line; circle; **angle**; measured, simulated, and normative values display; **values color-coding**	Line; circle; angle; measured, simulated, and normative values display; values color-coding
Feature - Spine measurements tools	Llordo; TKypho; pelvic; T1SPi; SVA; **SA Analysis**; **Sagittal wizard**; **Coronal wizard; Transitional anatomy (as part of SA Analysis or Sagittal wizard); Cervical**; Lenke classification; **Coronal correction factor**	Llordo; TKypho; pelvic; T1SPi; SVA; SA Analysis; Sagittal wizard; Coronal wizard; Transitional anatomy (as part of Sagittal wizard); Cervical; Lenke classification; Coronal correction factor
Feature - Surgical tools	Wedge; open; resect; wedge auto; open auto; resect auto; spondy	Wedge; open; resect; wedge auto; open auto; resect auto; spondy
Feature - Implants tools	Free Rod; cage; screw; screw selection; Rod Auto; cage auto; screw wizard; postop screw	Free Rod; cage; screw; screw selection; Rod Auto; cage auto; screw wizard; postop screw
Feature - Implants database	Adaptix PLIF, Capstone Control PLIF, Capstone PLIF, Clydesdale, Crescent, Divergence, IB3D PL, Pivox, Sovereign	Adaptix PLIF, Capstone Control PLIF, Capstone PLIF, Clydesdale, Crescent, Divergence, IB3D PL, Pivox, Sovereign
Feature - AI algorithms	**Degenerative; Adult Deformity; Pediatric Deformity**	Degenerative; Adult Deformity; Pediatric Deformity
Features - UNiD™ plan export	• As an image (.jpeg) • As a ZIP file comprising: - The initial image w/ and w/o measures (.jpeg) - The plan simulated image (.jpeg) - The rod geometric parameters (.txt) - All the drawn tools geometric parameters (.txt) - The measures (.csv) • To **Gaiteway™** to request plan validation	• As an image (.jpeg) • As a ZIP file comprising: - The initial image w/ and w/o measures (.jpeg) - The plan simulated image (.jpeg) - The rod geometric parameters (.txt) - All the drawn tools geometric parameters (.txt) - The measures (.csv) • To Medtronic HUB to request plan validation

Table 1: Substantial Equivalence Comparison

VII. Performance data	
Nonclinical tests	The following non-clinical performance data were provided in support of substantial equivalence: **Risk Management:** Assessment performed according to ISO 14971 and Medtronic procedures. All hazards and failures for the subject device have the same severity and occurrence as the predicate. No new or unresolved unknown hazards, hazardous situations and harm were identified. **Usability Assessment** Usability of the UNiD™ Spine Analyzer user interface was evaluated according to IEC 62366-1. The purpose was to assess new changes and ensure no usability issues could raise significant risks in terms of safety and effectiveness. **Software verification** The software verification is a combination of software code inspection, code review, software unit test, integration testing, non-regression testing and cybersecurity verification to ensure the software is developed correctly and adheres to its design specifications. Software verification was conducted on the UNiD™ Spine Analyzer in accordance with IEC 62304. **Software validation** The software validation was performed through user acceptance testing to ensure the software satisfies the specified requirements and meets the user's needs. It was conducted on the UNiD™ Spine Analyzer in accordance with IEC 82304-1. **Statistical Assessment part of Design Validation activity** The assessment supports that the input data (femoral head centers or bifemoral mid-point) obtained through the indirect method do not compromise the validity of the Degenerative Predictive Model (DPM) v2.0 outputs. Comparative analysis demonstrated no significant difference in predictive outputs.
Clinical tests	No clinical testing was used to support this submission.
VIII. Conclusion	
Based on the information contained in this submission, the subject UNiD™ Spine Analyzer v5.1.0 device is substantially equivalent to the following predicate device: UNiD™ Spine Analyzer v5.0.0 (K251629, S.E. 08/07/2025)	